510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel-GE Care Innovations, LLC
Address:	3721 Douglas Blvd, #100, Roseville, CA 95661
Telephone:	916.847.7794
Contact Person:	Maureen Glynn
Date Prepared:	March 20th 2013

AUG 09 2013

Device Information

Trade Name:	Intel-GE Care Innovations™ Connect RCM
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence of intended use is claimed to the following Over the Counter devices:

1. Intel-GE Care Innovations Guide **(K130290)**
2. Wellaho Personalized Outpatient Management System **(K123671)**
3. Vignet Telehealth Manager **(K113446)**

Device Description

Care Innovations™ Connect RCM is a software application for use with measurement devices commercially available for home use. The software executes on a web server and is accessed via a browser from the patient's COTS personal computing device. A small validated software application known as Device Connector runs on patients' home COTS platforms. Off the Shelf (OTS) software is also used with the internally developed software to provide functionality such as; setting & receiving email and text-based notifications, creating & editing calendar entries, playing Learn More videos, and holding a video conference with a clinician.

Care Innovations™ Connect RCM is a software application for use with measurement devices commercially available for home use. Connect RCM provides the same client capabilities of collecting and transmitting patient data to the clinician database system as the predicate devices, and uses the existing clinician database system in the Intel-GE Care Innovations™ Guide (K130290). No changes were required to the existing clinician database system to support the new client software.

Patients can also enter measurement data manually. The manually entered data is stored in the backend clinician database as well as the Personal Health Data Record. It is flagged as manually entered data.

Indications for Use

Intel-GE Care Innovations Connect RCM is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in videoconferences with caregivers and answer the caregivers' questions by participating in surveys.

Care Innovations Connect RCM is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

Care Innovations Connect RCM is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Care Innovations Connect RCM will be available for over the counter use.

Technological Characteristics

Connect RCM is substantially equivalent to the technology predicate device, the Intel-GE Care Innovations Guide (K130290), in terms of data collection software functionality, communication method of patient's COTS platform with backend server, types of third-party physiological measurement devices which can be interfaced to the patient's COTS platform, implementation method of collecting data from third-party devices, third party device driver software, connectivity, communication protocol, and display method.

Table 1: Peripherals Comparison between the intended use predicate devices and Connect RCM

Physiological Parameter	***Vignet Telehealth Manager (K113446)***	***Intel-GE Care Innovations Guide (K103290)***	***Intel-GE Care Innovations Connect RCM (K130821)***
Blood Pressure	A&D UA-767-PBT A&D UA-851-	A&D UA-767PC (K982481)	A&D UA-767PC (K982481)

	PBT		
Weight	A&D UC-321PBT Omron Weight Scale TD-3250C	A&D UC-321PBT (exempt) A&D UC-321PL (exempt)	A&D UC-321PBT (exempt) A&D UC-321PL (exempt)
Blood Glucose Level	Entra Health Systems MGH-BT1 (K081703) Fora Care, Inc. Taidoc Technology TD-3250C	Bayer Diagnostics Ascensia Breeze2 (K062347) Bayer Diagnostics Ascensia Contour Blood Glucose Monitoring System (K062058) LifeScan OneTouch Ultra Family of Blood Glucose Monitoring Systems (K043197) LifeScan OneTouch Ultra 2 of Blood Glucose Monitoring Systems (K053529)	Bayer Diagnostics Ascensia Breeze2 (K062347) Bayer Diagnostics Ascensia Contour Blood Glucose Monitoring System (K062058) LifeScan OneTouch Ultra Family of Blood Glucose Monitoring Systems (K043197) LifeScan OneTouch Ultra 2 of Blood Glucose Monitoring Systems (K053529)
Oxygen Saturation		Nonin 4100 Pulse Oximeter (K043359) Onyx® II 9560 (K081285)	Nonin 4100 Pulse Oximeter (K043359) Onyx® II 9560 (K081285)

Table 2: Main difference between Connect RCM meeting minimum specifications and the technology predicate device

Parameter	Intel-GE Care Innovations™ Health Guide (K130290)	Connect RCM (K130821)
Software Safety Standard	AAMI/ANSI/IEC ES 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	AAMI/ANSI/IEC ES 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Hardware Safety Standard	UL 60950-1:2007 Information Technology Equipment – Safety – Part 1: General Requirements	N/A

Safety and Efficacy

Connect RCM does not rely on an assessment of clinical performance data. The device will conform to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device has the same functionality as the predicate device, the Intel-GE Care Innovations Guide (K130290), and introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Intel-GE Care Innovations, LLC
c/o Ms. Maureen Glynn
3721 Douglas Blvd, #100
Roseville, CA 95661

Re: K130821
Trade/Device Name: Intel-GE Care Innovations Connect RCM
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II (two)
Product Code: DRG
Dated: July 8, 2013
Received: July 11, 2013

Dear Ms. Glynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number: _____

Device Name: Intel-GE Care Innovations™ Connect RCM

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Care Innovations Connect RCM will be available for over the counter use.

Prescription Use _____ AND/OR Over-The-Counter Use ____X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.08.09
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